

200.1079CON6

**UNITED STATES PATENT AND TRADEMARK OFFICE**

Examiner: Not Yet Known

Art Unit: 1614

Re: Application of:

Ronald M. BURCH, et al.

Serial No.:

10/057,631

Filed:

January 25, 2002

For:

**ANALGESIC COMBINATION OF  
OXYCODONE AND 5-(4-FLUOROPHENYL)-  
1-[4-(METHYLSUFONYL)PHENYL]-3-  
TRIFLUOROMETHYL 1H-PYRAZOLE**

**INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

November 25, 2002

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97(b), Applicants hereby make of record the references listed on the accompanying Form PTO-1449 (3 pages) and the following copies of Information Disclosure Statements (15 pages) submitted during the prosecution of the parent application U.S. Serial No. 09/154,354. The following are enclosed as Exhibit A:

- Information Disclosure Statement of June 7, 1999 (2 pages);
- Information Disclosure Statement of June 7, 1999 (2 pages);
- Information Disclosure Statement of June 7, 1999 (2 pages);
- Information Disclosure Statement of February 4, 2000 (2 pages);
- Information Disclosure Statement of September 26, 2001 (2 pages);
- Information Disclosure Statement of September 13, 2002 (3 pages); and
- Information Disclosure Statement of October 1, 2002 (2 pages).

**RECEIVED**

**DEC 05 2002**

**TECH CENTER 1600/2900**

It is noted that the Information Disclosure Statement of September 13, 2002, refers to Appendix A, which is a Statement of Grounds and Particulars in Support of Opposition dated June 14, 2002, brought by Pharmacia Corporation at the Australian Patent Office opposing Australian Patent Application No. 742097 (93984/98), the corresponding Australian application

of the parent U.S. application (Serial No. 09/154,354), and Appendix B, which is a copy of the current claims of Australian Patent Application No. 742097 (93984/98) which claims the same priority as the present application. In addition, Information Disclosure Statement of October 1, 2002, refers to Appendix A, an amendment of the Statement of Grounds and Particulars in Support of Opposition dated August 14, 2002. Specifically, Appendix A lists a further document (referenced in the Statement as D38) in addition to the references listed in Appendix A of the Information Disclosure Statement filed on September 13, 2002. Furthermore, reference D38 corresponds to reference AH in the Form PTO-1449 submitted on October 1, 2002.. These Appendices and attachments are not enclosed as these documents have already been made of record in the parent application.

Applicants respectfully point out to the Examiner that the PTO-1449 forms accompanying this Information Disclosure Statement list the references cited in Opposition to the corresponding Australian Patent Application No. 742097 (93984/98) of the parent U.S. Application (Serial No. 09/154,354. Copies of these references were submitted in the parent case (Serial No. 09/154,354) along with the above-referenced Information Disclosure Statements of September 13, 2002 (references AA through BM of Form PTO-1449) and October 1, 2002 (reference AH of page 1 of 1 of Form PTO-1449). Accordingly, pursuant to 37 CFR § 1.98(d), copies of the references listed on the accompanying Form PTO-1449 are not enclosed as these references have already been made of record. If it is determined that any of the listed references are not of record, the Examiner is requested to contact the undersigned so that a copy can be promptly forwarded.

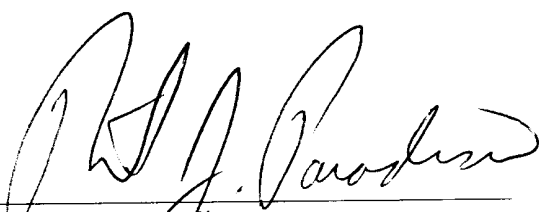
This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) before the mailing date of a First Office Action on the merits. Therefore, no fee is believed to be due for filing this Information Disclosure Statement. If it is determined that any fees are due, the Assistant Commissioner is hereby authorized to charge said fees to Deposit Account No. 50-0552.

It is respectfully requested that the references cited in the accompanying Form PTO-1449 be considered by the Examiner and made of record. If any of the listed references are found to be missing, the Examiner is requested to contact the undersigned so that a copy may be promptly forwarded.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: \_\_\_\_\_

  
Robert J. Paradiso  
Reg. No. 41,240

Davidson, Davidson & Kappel, LLC  
485 Seventh Avenue, 14th Floor  
New York, New York 10018  
(212) 736-1940

FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:  
200.1079US

SERIAL NO.: 09/154,354

## LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): Ronald M. BURCH, et al.

FILING DATE:  
September 17, 1998

GROUP: 1627

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLAS S	TRANSLATION	
													YES	NO
	AA	0	6	5	4	2	6	3	05/24/95	EP (A1)	A61K	31/135		
	AB	0	6	5	4	2	6	3	05/24/95	EP (B1)	A61K	31/135		
	AC	9	7	1	7	9	7	8	05/22/97	WO	A61K	33/00		
	AD	9	7	2	5	9	8	8	07/24/97	WO	A61K	31/495		
	AE	9	7	3	2	8	5	7	09/12/97	WO	C07D	241/104		

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AF	Dray et al. New Pharmacological Strategies for Pain Relief. <u>Annual Review of Pharmacology &amp; Toxicology</u> , 36, pp. 253-280. (1996).
AG	Brasseur, L. Revue des therapeutiques pharmacologiques actuelles de la douleur. <u>Drugs</u> , 53 Suppl 2, pp. 10-17. (1997)
AH	Rang et al. New molecules in analgesia. <u>British Journal of Anesthesia</u> , 75, pp. 145-156 (1995)
AI	Beaver, WT. Combination Analgesics. <u>American Journal of Medicine</u> , 77 (Suppl 3A), pp. 38-53. (1984).
AJ	Beaver, WT. Chapter 29: Nonsteroidal Antiinflammatory Analgesics and Their Combinations with Opioids. In <u>Evaluation and Treatment of Chronic Pain</u> , 2 <sup>nd</sup> ed., William & Wilkins pp. 363-383. (1992).
AK	Goodman & Gilman's. The Pharmacological Basis of Therapeutics, 9 <sup>th</sup> Edition. McGraw-Hill, New York, pp 535 and 551-552.
AL	Picard et al. Ketorolac potentiates morphine in postoperative patient-controlled analgesia. <u>Pain</u> , 73, 3 pp. 401-406. (1997).
AM	Elches et al. Continuous Intravenous Administration of Ketorolac Reduces Pain and Morphine Consumption After Total Hip or Knee Arthroplasty. <u>Anesthesia &amp; Analgesia</u> , 81 (6), pp. 1175-1180. (1995).
AN	Hoddsman et al. The morphine sparing effects of diclofenac sodium following abdominal surgery. <u>Anaesthesia</u> , 42(9), pp. 1005-1008. (1987).
AO	Kaasalainen et al. Developments in the treatment of cancer pain in Finland: The third nation-wide survey. <u>Pain</u> , 70, 2-3, pp. 175-183. (1997).
AP	Sunshine et al. Analgesic Efficacy of a Hydrocodone with Ibuprofen Combination Compared with Ibuprofen Alone for the Treatment of Acute Postoperative Pain. <u>Journal of Clinical Pharmacology</u> , 37 (10), pp. 908-915. (1997).
AQ	Insel. Chapter 27: Analgesic-Antipyretic and Anti-inflammatory Agents. In Hardman, ed., <u>Goodman &amp; Gilman's The Pharmacological Basis of Therapeutics</u> , 9 <sup>th</sup> Edition. McGraw-Hill, New York, pp. 654-655. (1996).
AR	Polisson. Non-steroidal Anti-inflammatory Drugs: Practical and Theoretical Consideration in Their Selection. <u>The American Journal of Medicine</u> , 100 (Suppl 2A), pp. 2A-31S - 2A-36S. (1996).
AS	Vane, J. Towards a better aspirin. <u>Nature</u> , 367, pp. 215-216. (1994).
AT	Simon, L.S. Nonsteroidal Antiinflammatory Drugs and Their Effects: The Importance of COX 'Selectivity'. <u>Journal of Clinical Rheumatology</u> , 2 (3), pp. 135-140. (1996).

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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DEC 05 2002

TECH CENTER 1600/2900

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1079US		SERIAL NO.: 09/154,354	
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Ronald M. BURCH, et al.			
				FILING DATE: September 17, 1998		GROUP: 1627	
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	BA	Van Ryn et al. Selective cyclooxygenase-2 inhibitors: pharmacology, clinical effects, and therapeutic potential. <u>Expert Opinion On Investigational Drugs</u> , pp. 609-614. (1997).					
	BB	Vane et al. New insights into the mode of action of anti-inflammatory drugs. <u>Inflammation Research</u> , 44, (No.1), pp 1-10 (1995).					
	BC	Engelhardt. Meloxicam: A Preferential Inhibitor of COX-2. <u>British Journal of Rheumatology</u> , 34, Abstract Suppl. 1, p. 48. (1995). Abstract.					
	BD	Lane, N.E. Pain Management in Osteoarthritis: The Role of COX-2 Inhibitors. <u>Journal of Rheumatology</u> , Vol. 24, Suppl 49, pp. 20-24. (1997).					
	BE	Boyce et al. L-745,337: A Selective Inhibitor of Cyclooxygenase-2 Elicits Antinociception But Not Gastric Ulceration in Rats. <u>Neuropharmacology</u> Vol. 33, pp. 1609-1611. (1994).					
	BF	Donnelly et al. COX-II Inhibitors - a new generation of safer NSAIDS? <u>Alimentary Pharmacology and Therapeutics</u> , 11, 2, pp. 227-236. (1997).					
	BG	Wallace, J.L. Nonsteroidal Anti-inflammatory Drugs and Gastroenteropathy: The Second Hundred Years. <u>Gastroenterology</u> , 112, 3, pp. 1000-1016. (1997).					
	BH	Robinson, D.R. Regulation of Prostaglandin Synthesis by Antiinflammatory Drugs. <u>J Rheumatology</u> , 24, Suppl. 47, pp. 32-39. (1997).					
	BI	Tannenbaum et al. An Evidence-Based Approach to Prescribing NSAIDS in Musculoskeletal Disease: A Canadian Consensus. <u>Canadian Medical Association Journal</u> , 155, 1, pp. 77-88. (1996).					
	BJ	Mehlsch et al. Analgesic Efficacy and Plasma Levels of a Highly Selective Inhibitor of COX-2 (SC-58635, SC) in Patients with Postsurgical Dental Pain. <u>Journal of Clinical Pharmacology</u> , 37, 9, 863. (1997). Abstract.					
	BK	Dammann. Selective COX-2 Inhibition: Its Relevance for NSAID-Gastrointestinal Toxicity. <u>Gut</u> , 39, Suppl. 3, A151. (1996). Abstract.					
	BL	Penning et al. Synthesis and Biological Evaluation of the 1, 5 -diarylpyrazole class of cyclooxygenase-2 Inhibitors: Identification of 4-[5-(4-methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide (SC-58635, Celecoxib). <u>Journal Of Medicinal Chemistry</u> , 40(9), 1347-65. (1997).					
	BM	Lipsky et al. Outcome of Specific COX-2 Inhibition in Rheumatoid Arthritis. <u>Journal Of Rheumatology</u> , 24 Suppl 49, pp. 9-14. (1997).					
	BN						
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	BP						
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	BS						
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EXAMINER				DATE CONSIDERED			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

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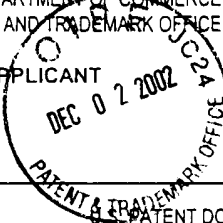
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FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:  
200.1079USSERIAL NO.:  
09/154,354

## LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): Ronald M. BURCH, et al.

FILING DATE:  
September 17, 1998GROUP:  
1627

U.S. PATENT DOCUMENTS									
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE
									NAME
									CLASS
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	AA								
	AB								
	AC								
	AD								
	AE								
	AF								
	AG								

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	AH	0	7	3	4	2	7	5	11/04/1997	Australia	C07D	261/08		
	AI													
	AJ													
	AK													
	AL													

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AM	
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EXAMINER

DATE CONSIDERED

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DEC 05 2002

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Exhibit A

200.1079US

UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: K. McMILLAN                      Art Unit: 1614  
Re:    Application of:                      Ronald M. BURCH, et al.  
      Serial No.:                              09/154,354  
      Filed:                                    September 17, 1998  
      For:                                      SYNERGISTIC ANALGESIC COMBINATION  
                                                 OF OPIOID ANALGESIC AND  
                                                 CYCLOOXYGENASE-2 INHIBITOR

INFORMATION DISCLOSURE STATEMENT NO. 1

Assistant Commissioner for Patents  
Washington, D.C. 20231

June 7, 1999

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application.

This Information Disclosure Statement and Form PTO-1449 is filed before the mailing of a first Office Action on the merits. Accordingly, it is believed that no fees are due. However, if it is determined that any fees are due, the Assistant Commissioner is authorized to charge payment of the same to Deposit Account No. 50-0552. A duplicate copy of this sheet is enclosed.

The Examiner's particular attention is directed to U.S. Patent No. 5,859,257, particularly column 4, lines 33-39 (referenced as 'AA' on the enclosed PTO-1449 Form). The Examiner's attention is also directed to U.S. Patents No. 5,863,922, 5,840,731 and 5,869,498 (referenced as

I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with the United States Postal Service as "first class mail" in an envelope addressed to "Assistant Commissioner for Patents, Washington, D.C. 20231" on June 7, 1999.  
DAVIDSON, DAVIDSON & KAPPEL, LLC

BY: Jacqueline B. Swartz

'AB' 'AC' and 'AD' on the enclosed PTO-1449 Form) which are related to combinations of NMDA antagonists with opioids and NSAIDS (non-steroidal anti-inflammatory drugs). The Examiner's attention is further directed to the reference cited as 'AP' on the enclosed PTO-1449 Form, Comparative Analgesic Efficacy of Nimesulide and Diclofenac Gels after Topical Application on the Skin. This reference relates to the comparative analgesic efficacy of nimesulide and diclofenac.

Identification of the references provided herewith is not to be construed as an admission by the Applicants or their representatives that such references are available as "prior art" against the present application.

It is respectfully requested that the references cited in the accompanying PTO-1449 form be considered and made of record.

Although the undersigned has attempted to direct the Examiner's attention to particular sections of certain of the enclosed references, the undersigned wishes to make clear that such comments made herein are not intended to be an indication that the other sections of those references are not pertinent; nor is it meant to be taken that the remaining cited references are necessarily less pertinent. The Examiner is encouraged to carefully review each and every one of the references cited in this Information Disclosure Statement on his own and draw his own conclusions as to their pertinence.

Respectfully Submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC



Clifford M. Davidson

Reg. No. 32,728

Davidson, Davidson & Kappel, LLC  
1140 Avenue of the Americas, 15th Floor  
New York, New York 10036  
(212) 997-1028



UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: K. McMILLAN

Art Unit: 1614

Re: Application of:

Ronald M. BURCH, et al.

Serial No.:

09/154,354

Filed:

September 17, 1998

For:

SYNERGISTIC ANALGESIC COMBINATION  
OF OPIOID ANALGESIC AND  
CYCLOOXYGENASE-2 INHIBITOR

INFORMATION DISCLOSURE STATEMENT NO. 2

Assistant Commissioner for Patents  
Washington, D.C. 20231

June 7, 1999

Sir:

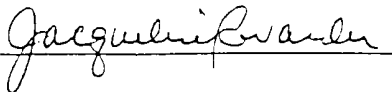
In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application.

This Information Disclosure Statement and Form PTO-1449 is filed before the mailing of a first Office Action on the merits. Accordingly, it is believed that no fees are due. However, if it is determined that any fees are due, the Assistant Commissioner is authorized to charge payment of the same to Deposit Account No. 50-0552. A duplicate copy of this sheet is enclosed.

The references cited on the enclosed PTO-1449 Form relate to various compositions containing opioids and non-steroidal anti-inflammatory agents (commonly referred to as 'NSAIDS').

I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with the United States Postal Service as "first class mail" in an envelope addressed to "Assistant Commissioner for Patents, Washington, D.C. 20231" on June 7, 1999.  
DAVIDSON, DAVIDSON & KAPPEL, LLC

BY:



Identification of the references provided herewith is not to be construed as an admission by the Applicants or their representatives that such references are available as "prior art" against the present application.

It is respectfully requested that the references cited in the accompanying PTO-1449 form be considered and made of record.

Respectfully Submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

A handwritten signature in cursive script, appearing to read "Clifford M. Davidson", is written over a horizontal line.

Clifford M. Davidson

Reg. No. 32,728

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UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: K. McMILLAN

Art Unit: 1614

Re: Application of:

Ronald M. BURCH, et al.

Serial No.:

09/154,354

Filed:

September 17, 1998

For:

SYNERGISTIC ANALGESIC COMBINATION  
OF OPIOID ANALGESIC AND  
CYCLOOXYGENASE-2 INHIBITORINFORMATION DISCLOSURE STATEMENT NO. 3Assistant Commissioner for Patents  
Washington, D.C. 20231

June 7, 1999

Sir:

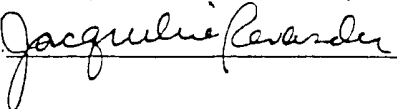
In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application.

This Information Disclosure Statement and Form PTO-1449 is filed before the mailing of a first Office Action on the merits. Accordingly, it is believed that no fees are due. However, if it is determined that any fees are due, the Assistant Commissioner is authorized to charge payment of the same to Deposit Account No. 50-0552. A duplicate copy of this sheet is enclosed.

The references cited on the enclosed PTO-1449 Form relate to compounds described as being useful in the treatment of cyclooxygenase-2 mediated disease states. Reference 'AM' is cited for its discussion of COX-2 and COX-1 activity.

I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with the United States Postal Service as "first class mail" in an envelope addressed to "Assistant Commissioner for Patents, Washington, D.C. 20231" on June 7, 1999.  
DAVIDSON, DAVIDSON & KAPPEL, LLC

BY:



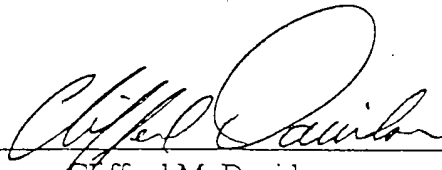
The Examiner's particular attention is directed to U.S. Patents No. 5,409,944 and 5,436,265, referenced on the enclosed PTO-1449 Form as 'AA,' and 'AB.' These patents describe, *inter alia*, compounds with cyclooxygenase-2 inhibitory properties in combination with "antitussives including codeine, hydrocodone, caramiphen, carbetapentane or dextromethorphan." (See column 6, lines 33-35 of the '944 patent, and column 5, lines 48-50 of the '265 patent). The Examiner's attention is also directed to U.S. Patent No. 5,521,213, referenced on the enclosed PTO-1449 Form as 'AD.' This patent discloses, *inter alia*, "[a compound for treating cyclooxygenase-2 mediated diseases] and one or more ingredients such as another pain reliever including acetaminophen or phenacetin . . . an antitussive including codeine, hydrocodone, caramiphen, carbetapentane or dextromethorphan . . . ." (See column 6, lines 7-15). A similar disclosure is also found in U.S. Patent No. 5,550,142 referenced on the enclosed PTO-1449 Form as 'AE,' at column 7, line 56 - column 8, line 5, U.S. Patent. 5,552,422, referenced on the enclosed PTO-1449 Form as 'AF,' at column 9, line 59 - column 10, line 7, U.S. Patent 5,604,253, referenced on the enclosed PTO-1449 Form as 'AG,' at column 10 line 66 - column 11, line 14, and U.S. patent 5,639,780, referenced on the enclosed PTO-1449 Form as 'AH,' at column 11, lines 36-51.

Identification of the references provided herewith is not to be construed as an admission by the Applicants or their representatives that such references are available as "prior art" against the present application.

It is respectfully requested that the references cited in the accompanying PTO-1449 form be considered and made of record.

Respectfully Submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

  
Clifford M. Davidson  
Reg. No. 32,728

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UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: K. McMILLAN

Art Unit: 1614

Re: Application of:

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CYCLOOXYGENASE-2 INHIBITOR

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

February 4, 2000

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application.

This Information Disclosure Statement and Form PTO-1449 is filed before the mailing of a first Office Action on the merits. Accordingly, it is believed that no fees are due. However, if it is determined that any fees are due, the Assistant Commissioner is authorized to charge payment of the same to Deposit Account No. 50-0552. A duplicate copy of this sheet is enclosed.

The references cited on the enclosed PTO-1449 Form describe various COX-2 inhibitors, including 4-[4-(methylsulfonyl)phenyl]-3-phenyl-2(5H)-furanone (rofecoxib), the elected species set forth in the claims as amended.

I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with the United States Postal Service as "first class mail" in an envelope addressed to "Assistant Commissioner for Patents, Washington, D.C. 20231" on February 4, 2000.  
DAVIDSON, DAVIDSON & KAPPEL, LLC

BY: 

The references further describe the COX-2 inhibitors described therein in combination with "one or more ingredients such as another pain reliever including acetaminophen or phenacetin;...[and] an antitussive including codeine, hydrocodone, ...." (See column 8 of the '955 patent, and column 13 of the '374 patent). This is the same discussion included in other patents assigned to Merck Frosst Canada Inc., which was previously pointed out to the Examiner in the Information Disclosure Statement filed June 7, 1999. Oxycodone is not included in this discussion.

Identification of the references provided herewith is not to be construed as an admission by the Applicants or their representatives that such references are available as "prior art" against the present application.

It is respectfully requested that the references cited in the accompanying PTO-1449 form be considered and made of record.

Respectfully Submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC



Clifford M. Davidson

Reg. No. 32,728

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New York, New York 10036  
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UNITED STATES PATENT AND TRADEMARK OFFICE

200.1079US

Re: Application of: BURCH et al.  
Serial No.: 09/154,354  
Group No.: 1627  
Filed: September 17, 1998  
For: SYNERGISTIC COMBINATION OF OPIOID ANALGESIC  
AND CYCLOOXYGENASE-2 INHIBITOR

Information Disclosure Statement under 37 C.F.R. § 1.97(b)(4) or alternatively under 37  
C.F.R. § 1.97(c)(1) with accompanying statement under 37 C.F.R. § 1.97(e)

Assistant Commissioner for Patents  
Washington, D.C. 20231

September 26, 2001

Sir:

In accordance with Applicant's duty of disclosure under 37 C.F.R. § 1.56 and pursuant to 37 C.F.R. § 1.97(b)(4), Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified application. It is believed that this Information Disclosure Statement is submitted before a first Office Action after the filing of a request for continued examination, therefore no fee is due.

In the event an Office Action has been mailed, this Information Disclosure Statement is filed under 37 C.F.R. § 1.97(c)(1) with a statement under 37 C.F.R. § 1.97(e) declaring that each item of information contained in the Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

I hereby certify that the documents referred to as attached therein and/or fee are being deposited with the United States Postal Service with sufficient postage as "first class mail" in an envelope addressed to "Assistant Commissioner for Patents, Washington, D.C. 20231" on September 26, 2001.

DAVIDSON, DAVIDSON & KAPPEL, LLC

BY: J. Daniel Fantarot

It is pointed out to the Examiner that all of the cited references (AE through AO) were cited in the European Search Report from the corresponding European application. A copy of the search report is enclosed.

It is respectfully requested that the references cited on the accompanying PTO Form-1449 be considered and made of record. If any of the publications listed thereon are missing, the Examiner is requested to contact the undersigned so that a copy can be promptly forwarded.

In the event that it is determined that any additional fee is due, the Examiner is authorized to charge said fee to DAVIDSON, DAVIDSON & KAPPEL, LLC, Deposit Account No. 50-0552. A duplicate copy of this sheet is enclosed.

It is respectfully submitted that the pending claims are patentable over all the references made of record at this time.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 

Robert J. Paradiso  
Reg. No. 41,240

Davidson, Davidson & Kappel, LLC  
485 Seventh Avenue, 14<sup>th</sup> Floor  
New York, New York 10018  
(212) 736-1940



UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: K. McMILLAN                      Art Unit: 1614  
Re:    Application of:                      Ronald M. BURCH, et al.  
      Serial No.:                              09/154,354  
      Filed:                                    September 17, 1998  
      For:                                      ANALGESIC COMBINATION OF  
                                                 OXYCODONE AND ROFECOXIB

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §1.56

Box: ISSUE FEE  
Assistant Commissioner for Patents  
Washington, D.C. 20231

September 13, 2002

Sir:

In accordance with the provisions of 37 C.F.R. §§ 1.56 and 1.97, Applicants hereby make of record the following: Statement Of Ground and Particulars in Support of Opposition attached as Appendix A (20 pages); Claims of Australian Patent Application No. 742097 (93984/98) attached as Appendix B (5 pages); and Form PTO-1449 (2 pages) with copies of cited references pursuant to 37 C.F.R. § 1.98(d).

Attached as Appendix A is a Statement of Grounds and Particulars in Support of Opposition dated June 14, 2002, brought by Pharmacia Corporation at the Australian Patent Office opposing Australian Patent Application No. 742097 (93984/98), the corresponding Australian application of the present U.S. application.

Attached as Appendix B is a copy of the current claims of Australian Patent Application No. 742097 (93984/98), which claims the same priority as the present application.

References D1 to D7 (pages 2 to 4 of the statement of Appendix A), D9 to D16 (pages 5 to 7 of the statement of Appendix A) and D21 to D37 (pages 8 to 11 of the statement of Appendix A), correspond to references AA through BM of attached Form PTO-1449.

References D8 (page 5 of the statement of Appendix A) and D17 to D20 (page 7 to page 8 of the statement of Appendix A) are not listed on the accompanying Form PTO-1449 as these references have already been made of record in the present application. Specifically, reference D8 was cited as reference AA (on Form PTO-1449 labeled 1 of 1) and references D17, D18, D19, and D20 were cited as references BB, BD, BF, and BH, respectively, (on Form PTO-1499 labeled 2 of 2), in the Information Disclosure Statement filed June 7, 1999.

This Information Disclosure Statement and accompanying Form PTO-1449 are being filed after a notice of allowance under §1.311 but before the payment of the issue fee in accordance with C.F.R. §§ 1.97(d) and 1.97(e).

In accordance with C.F.R. § 1.97(e)(2), it is stated that no item of information contained in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three (3) months prior to the filing of this Information Disclosure Statement.

A check in the amount of \$180.00 is enclosed to satisfy the fee requirement due under 1.17(p) for filing this Information Disclosure Statement.

It is respectfully requested that the references cited in the accompanying Form PTO-1449 be considered by the Examiner and made of record. If any of the listed references are missing, the Examiner is requested to contact the undersigned so that a copy may be promptly forwarded.

In the event any additional fee is due or overpayment made in connection with the filing of this Information Disclosure Statement, the Assistant Commissioner is hereby authorized to charge said deficiency or credit overpayment to our Deposit Account No. 50-0552.

Respectfully Submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 

Robert J. Paradiso  
Reg. No. 41,240

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485 Seventh Avenue, 14<sup>th</sup> Floor  
New York, New York 10018  
(212) 736-1940

UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: Bennett M. CELSA

Art Unit: 1627

Re: Application of:

Ronald M. BURCH, et al.

Serial No.:

09/154,354

Filed:

September 17, 1998

For:

ANALGESIC COMBINATION OF  
OXYCODONE AND ROFECOXIBSUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §1.56

Box: ISSUE FEE

October 1, 2002

Assistant Commissioner for Patents

Washington, D.C. 20231

Sir:

Applicants hereby make of record the reference cited on the attached Form PTO-1449 and Appendix A, which is an amendment of the Statement of Grounds and Particulars in support of Opposition previously submitted in the Information Disclosure Statement filed September 13, 2002.

The Pharmacia Corporation, the Opponent of the corresponding Australian application requested amendment of their Statement to include a further document (referenced in the Statement as 38D). A marked-up copy of the Statement showing the amendments is attached as Appendix A, and the further document is cited as reference AA in the attached PTO-1449 Form.

This Information Disclosure Statement and accompanying Form PTO-1449 are being filed after a notice of allowance under §1.311 but before the payment of the issue fee in accordance with C.F.R. §§ 1.97(d) and 1.97(e).

In accordance with C.F.R. § 1.97(e)(2), it is stated that no item of information contained in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement

was known to any individual designated in 37 CFR 1.56(c) more than three (3) months prior to the filing of this Information Disclosure Statement.

A check in the amount of \$180.00 is enclosed to satisfy the fee requirement due under 1.17(p) for filing this Information Disclosure Statement.

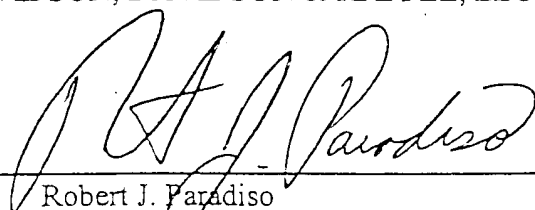
It is respectfully requested that the reference cited in the accompanying Form PTO-1449 be considered by the Examiner and made of record. If this reference is found to be missing, the Examiner is requested to contact the undersigned so that a copy may be promptly forwarded.

In the event any additional fee is due or overpayment made in connection with the filing of this Information Disclosure Statement, the Assistant Commissioner is hereby authorized to charge said deficiency or credit overpayment to our Deposit Account No. 50-0552.

Respectfully Submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By:

  
Robert J. Paradiso  
Reg. No. 41,240

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485 Seventh Avenue, 14<sup>th</sup> Floor  
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